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PTO/SB/08A (08-00)

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Substitute for form 1449A/PTO C mplete if Known **Application Number** To Be Assigned INFORMATION DISCLOSURE Filing Date August 29, 2001 STATEMENT BY APPLICANT First Named Inventor ROTHMAN et al. **Group Art Unit** To Be Assigned (use as many sheets as necessary) **Examiner Name** To Be Assigned Sheet of Attorney Docket Number 01107.00185

|                        |             |                 |                   | U.S. PATENT DOCUM             | IENTS                                  | TO =                                  |
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|                        |             | U.S. Patent Doc | ument             | Name of Patentee or Applicant | Date of Publication of                 | Pages, Columns, Lines, Where Relevant |
| Examiner<br>Initials * | Cite<br>No. | νία   ν:α       | of Cited Document | Cited Document MM-DD-YYYY     | Passages or Relevant<br>Figures Appear |                                       |
| € 2                    |             | 5,994,066       |                   | Bergeron et al.               | 11/30/1999                             |                                       |
| <u> </u>               |             | 6,001,564       |                   | Bergeron et al.               | 12/14/1999                             |                                       |
|                        | _           | 6,184,000       | B1                | Jones et al.                  | 02/06/2001                             |                                       |
| J                      |             | 5,407,797       |                   | Martiere et al.               | 04/18/1995                             |                                       |

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| Initials* | No. <sup>1</sup> | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup><br>( <i>if known</i> ) | or Applicant of<br>Cited Document | Cited Document<br>MM-DD-YYYY             | Passages or Relevant<br>Figures Appear | T <sub>6</sub> |
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|------------------------|--------------|---|----|
| Spc                    |              | Carroll, N.M. et al., "Elimination of Bacterial DNA from Taq DNA Polymerases by Restriction Endonuclease Digestion", <u>Journal of Clinical Microbiology</u> , Vol. 37, No. 10, (1999), pp. 3402-3404   |    |
|                        |              | Corless, C.E. et al., "Contamination and Sensitivity Issues with a Real-Time Universal 16S rRNA PCR", <u>Journal of Clinical Microbiology</u> , Vol. 38, No. 5, (2000), pp. 1747-1752   |    |
|                        |              | Lu, Jang-Jih, et al., "Use of PCR with Universal Primers and Restriction Endonuclease Digestions for Detection and Identification of Common Bacterial Pathogens in Cerebrospinal Fluid", <u>Journal of Clinical Microbiology</u> , Vol. 38, (2000), pp. 2076-2080 |    |
|                        |              | Sharma, J.K. et al., "A Simple Method for Elimination of Unspecific Amplifications in Polymerase Chain Reaction", Nucleic Acids Research, Vol. 20, No. 22, (1992), pp. 6117-6118  |    |

| Examiner<br>Signature | Bretha Cherndery | Date<br>Considered | 8/10/04 |
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## TRADEM Stitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known 09/940.860 **Application Number** August 29, 2001 Filing Date First Named Inventor Rothman et al. **TBA** Group Art Unit TBA **Examiner Name** 001107.00185 Attorney Docket Number

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|                   |  |  | U.S. PATENT D    | OCUMENTS   |   |  |
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| Examiner          | Cite   | Document Number                            | Publication Date | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant |  |
| Initials *        | No.1   | Number - Kind Code <sup>2</sup> (if known) | MM-DD-YYYY       |  | Figures Appear  |  |
| 812               | <del>                                     </del> | US-5,994,066                               | 11/30/1999       | Bergeron et al.                                    |   |  |
| <del>- 31 -</del> | 1  | US- 6,001,564                              | 12/14/1999       | Bergeron et al.                                    |   |  |
| t                 |  | US- 6,184,000                              | 02/06/2001       | Jones et al.                                       |   |  |
| 1                 |  | US- 5,407,797                              | 04/18/1995       | Marliere et al.                                    |   |  |
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| Examiner<br>Signature | Brabba Chundun | Date<br>Considered | 8/10/04 |
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First Named Inventor Rothman et al.

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Attorney Docket Number 001107.00185

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| Examiner  |                                       | Date        | $I = \mathcal{O}_{lm} I_{ml}$ |
|           | Rahha Chimdury                        | Considered  | 8/10/04                       |
| Signature | Bresha Chimawy                        | 00110100100 |                               |

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